

Siemens Medical Solutions USA, Inc.
Oncology Care Systems

JUN - 7 2006

Section 5
510(k) Summary

Submitter: Siemens Medical Solutions USA, Inc.
Oncology Care Systems Group
4040 Nelson Avenue
Concord, CA 94520

Contact: Ken Nehmer
Director, Regulatory Affairs

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Proprietary Name: COHERENCE Dosimetrist Workspace v2.2

Common Name: System, Planning, Radiation Therapy Treatment

Classification: 892.5050

Product Code: MUJ

Substantial Equivalence Claimed To:

VSIM K022036 (cleared on November 5, 2002)
Market name: COHERENCE Dosimetrist Workspace v2.0

KonRad, Model v2.0 K022307 (cleared on October 8, 2002)

The Food and Drug Administration was notified on August 22, 2003 that Siemens Medical Solutions USA, Inc. – Oncology Care Systems had acquired the radiation therapy assets formally owned by MRC Systems GMBH. The KonRad v2.0 (K022307) is one of those assets acquired from MRC by Siemens.

Description Summary:

The COHERENCE Dosimetrist Workspace v2.2 integrates the functionality of two previously released Siemens Medical Solutions USA, Inc. products (VSIM and KonRad, Model v2.0) with the addition of further enhancements to this pre-existing functionality. The integration allows for the sharing of data with all other application components within the COHERENCE Dosimetrist Workspace v2.2. This new software package is based on the syngo user interface standard which was cleared via K010938.

The existing functionality (as previously cleared by VSIM (K022036) and KonRad (K022307)) is described by the following components:

VSIM component

The VSIM component is intended to give the user general viewing and examination tools for viewing medical diagnostic images. Computed Tomography (CT) scans are the centerpiece of the diagnostic images used by the VSIM part of this component and it is possible to load other modality images, in conjunction with the CT images for treatment planning. The VSIM component is intended to provide tools for delineating and representing targets and critical

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structures. The component enables the user to design complex beam profiles and place them for optimum radiation therapy treatment. A three dimensional graphical representation allows for a virtual setup and treatment of the patient without involving the patient.

KonRad component

The KonRad component is a radiation therapy treatment planning package designed to optimize multi-leaf collimator (MLC) positions or partial attenuation block shapes for intensity modulated external beam radiation therapy (IMRT). The KonRad component uses defined anatomical structures for the optimization and treatment planning process. The images or contours are based on tomographic images imported via DICOM or DICOM RT protocols from various sources such as CT. The site-specific treatment machine beam data is utilized for plan calculation. The user defines the desired dose to be delivered to the target and the surrounding structures. Values are entered to weight the optimization calculations according to the importance of reaching the dose objectives for the target and other structures. The KonRad component will calculate the required MLC or partial attenuation block shapes needed to achieve the dose objectives. This process is done for each beam simultaneously and the resulting dose distribution and DVH are displayed. The input parameters can be modified and the optimization repeated until the user obtains their desired results. Once the desired treatment plan results are obtained, the user can store the final treatment plan for export. The final treatment plan can be exported to the appropriate delivery equipment, linear accelerator, and/or record and verify system. The export of the final treatment plan does not activate the radiation therapy delivery equipment, all information must be verified by the user prior to the initiation of radiation therapy treatment.

The new functionality that is being added with COHERENCE Dosimetrist Workspace v2.2 is described as follows:

VSIM component

- DICOM RT Plan and RT structure set can be imported and converted into VSIM compatible objects
- Functionality to allow contours/ports editing
- Beams eye view (BEV), collimator is rotated as opposed to the underlying image
- Improvements to the service user interface
- Support for DRR presets for organ-based windowing
- Spline fitting mode enabled for editing of contours/blocks
- Support for copying of plans is provided
- Verify and Record system taskcard integrated
- Various tool enhancements within the Localization Mode
- Auto fit functionality enhancements

KonRad component

- Compensator support
- Plan combination support to combine two IMRT plans to support multiple isocenters or large treatment volumes
- DICOM RT dose import and consideration of pre-planned/treated dose
- Plan and constraint template editor

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- Allow to optimize with MLC field size constraints
- Support IMRT for Siemens MLC (without using 6.5 cm leaves)
- Export DVH data in a easily readable format

Syngo™:

The original COHERENCE Dosimetrist Workspace software (K022036) was based on the software architecture of the previously cleared *syngo* software (K010938) and allows for a standardized graphical user interface across Siemens medical products. The *syngo*-based software design consists of task cards allowing for a selection of modules of common software applications for image acquisition, reconstruction, post-processing, display, and archiving across the Siemens medical product lines.

As part of the Siemens Medical Solutions family of workstations, the *syngo* based workstations (Oncology Care System calls a "workstation" a "workspace") offers a configurable selection of software applications depending on the type of *syngo* package that is required for a specific modality. There are multiple applications in common across all Siemens imaging modalities as previously mentioned.

The COHERENCE Dosimetrist Workspace v2.2, will be available as individual purchased options to medical linear accelerator product lines upon receipt of FDA market clearance notification.

Intended Use:

The intended use of the COHERENCE Dosimetrist Workspace is as an accessory to the linear accelerator systems to aid and support in the planning of delivery of x-ray radiation for the therapeutic treatment of cancer.

The COHERENCE Dosimetrist Workspace v2.2 encompasses a number of *syngo* software applications who's indication for use include the viewing, manipulation, filming, communications, and archiving of medical images and data on exchange media.

The COHERENCE Dosimetrist Workspace v2.2 is a comprehensive oncology workflow software package that allows for both CT simulation as well as inverse radiation therapy treatment planning and optimization in one software package to aid in oncology clinical workflow. This workspace is comprised of two major components, the CT Simulation component (VSIM) and the inverse radiation therapy treatment planning component (KonRad).

The VSIM component permits CT simulation to be performed on the *syngo* workstation. The CT scans are first loaded into the VSIM software component and the user is able to create three-dimensional models of targets and organs. The user is able to identify the patient isocenter, place treatment beams, and identify beam modifiers (blocks, apertures, and MLCs). The information is then available for radiation treatment planning for dose calculation via the KonRad software component or other treatment planning systems. The plans are then reviewed and approved by the clinician prior to transfer to the delivery system for the actual treatment.

The KonRad software component is intended to optimize multi-leaf (MLC) positions or partial attenuation block shapes for intensity modulated external beam radiation therapy (IMRT). Once the optimization is complete the dose distribution and dose volume histogram curves are displayed for the user to evaluate. After approval the results are exported to the delivery equipment, linear accelerator, or record and verify system, for final verification prior to treatment delivery. The KonRad software component allows for efficient inverse radiation therapy treatment planning and optimization.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 7 2006

Mr. Ken Nehmer
Director, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
Oncology Care Systems
4040 Nelson Avenue
CONCORD CA 94520

Re: K061097
Trade/Device Name: COHERENCE™ Dosimetrist Workspace v2.2
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: April 17, 2006
Received: April 19, 2006

Dear Mr. Nehmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K061097

Siemens Medical Solutions USA, Inc.
Oncology Care Systems

Section 4

Indication For Use Statement

510(k) Number (if known): K061097

Device Name: COHERENCE™ Dosimetrist Workspace v2.2

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Per 21 CFR 801.109)

OR
Nancy C. Haddon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061097